

AMENDMENTS TO THE CLAIMS

Claims 1-53 (Cancelled).

54. (Previously presented). A recombinant polynucleotide comprising at least one enhancer element obtained from intron 3 of the PSM gene operably linked to a sequence encoding a heterologous polypeptide.

55. (Previously presented). A recombinant polynucleotide according to claim 54 in which the recombinant polynucleotide further comprises a promoter.

56. (Previously presented). A recombinant polynucleotide according to claim 54 in which the promoter is located upstream from and is operably linked to the sequence encoding the heterologous polypeptide.

57. (Previously presented). A recombinant polynucleotide according to claim 55 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

58. (Previously presented). A recombinant polynucleotide according to claim 54 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

59. (Previously presented). A recombinant polynucleotide according to claim 58 in which the promoter active in the prostate is a PSM promoter.

60. (Cancelled)

61. (Previously presented). A recombinant polynucleotide according to claim 56 in which the enhancer element comprises:

- (a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or
- (b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions to a sequence defined in paragraph (a).

62. (Previously presented). A recombinant polynucleotide according to claim 54 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

63. (Previously presented). A recombinant polynucleotide according to claim 54 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency.

64. (Previously presented). A recombinant polynucleotide according to claim 54 in which the polynucleotide comprises two or more enhancer elements obtained from intron 3 of the PSM gene.

65. (Previously presented). A recombinant expression cassette comprising at least one enhancer element obtained from intron 3 of the PSM gene operably linked to a promoter, and an insertion site into which a coding sequence is optionally inserted, the insertion site being operably linked to and downstream of the promoter.

66. (Cancelled).

67. (Previously presented). A recombinant expression cassette according to claim 65 in which the enhancer element is upstream of the promoter.

68. (Cancelled).

69. (Previously presented). A recombinant expression cassette according to claim 65 in which the enhancer element comprises

- (a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or
- (b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions to a sequence defined in paragraph (a).

70. (Previously presented). A recombinant expression cassette according to claim 65 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions.

71. (Previously presented). A recombinant expression cassette according to claim 65 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions.

72. (Previously presented). A recombinant expression cassette according to claim 65 in which the expression cassette comprises two or more enhancer elements obtained from intron 3 of the PSM gene.

73. (Previously presented). A recombinant expression cassette according to claim 65 in which the expression cassette comprises a dimer or higher multimer comprising two or more enhancer elements derived from intron 3 of the PSM gene.

74. (Previously presented). A recombinant expression cassette according to claim 65 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase

(TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

75. (Previously presented). A recombinant expression cassette according to claim 74 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

76. (Previously presented). A recombinant expression cassette according to claim 75 in which the promoter active in the prostate is a PSM promoter.

77. (Previously presented). A recombinant expression cassette according to claim 65 in which the expression cassette further comprises a polyadenylation signal located downstream from and operably linked to the coding sequence or downstream from the insertion site.

78. (Previously presented). A recombinant expression cassette according to claim 77 in which the polyadenylation signal is the SV40 polyadenylation signal or the bovine growth hormone polyadenylation signal.

79. (Previously presented). An isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising

(a) a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11, or
(b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions to the sequence defined in paragraph (a).

80. (Previously presented). An isolated nucleic acid molecule, the nucleic acid molecule having enhancer activity and comprising

(a) a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11, or
(b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions to the sequence defined in paragraph (a).

81. (Previously presented). A recombinant polynucleotide comprising an isolated nucleic acid molecule of claim 79.

82. (Previously presented). A vector comprising an isolated nucleic acid molecule as claimed in claim 79.

83. (Previously presented). A vector according to claim 82 which further comprises a gene encoding a selectable marker.

84. (Previously presented). A vector according to claim 82 in which the vector is a human adenovirus Type 5 or ovine adenovirus.

85. (Currently amended). A method for directing expression of a coding sequence in a prostate cell, the method comprising introducing into the cell a recombinant expression cassette comprising at least one enhancer element obtained from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the enhancer~~regulatory~~ element and promoter direct expression of the coding sequence.

86. (Cancelled).

87. (Previously presented). A method according to claim 85 in which the enhancer element comprises

- (a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or
- (b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions to a sequence defined in paragraph (a).

88. (Previously presented). A method according to claim 85 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or

a sequence which hybridises thereto under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions.

89. (Previously presented). A method according to claim 85 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions.

90. (Currently amended). A method according to claim 85 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, or a promoter active in the prostate, ~~or a promoter active in the vascular endothelium.~~

91. (Previously presented). A method according to claim 90 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

92. (Previously presented). A method according to claim 91 in which the promoter active in the prostate is a PSM promoter.

93. (Cancelled).

94. (Cancelled).

95. (Currently amended). A method for the treatment of prostate cancer which method comprises administering to a subject a recombinant expression cassette comprising at least one enhancer element obtained from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the enhancer~~regulatory~~ element and promoter direct expression of the coding sequence.

96. (Cancelled).

97. (Previously presented). A method according to claim 95 in which the enhancer element comprises

- (a) a sequence comprising nucleotides 14,045 to 15,804, nucleotides 14,760 to 15,804, nucleotides 14,760 to 16,575 or nucleotides 14,045 to 16,575 of the PSM gene; or
- (b) a nucleic acid sequence which hybridises under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions to a sequence defined in paragraph (a).

98. (Previously presented). A method according to claim 95 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 14930 as shown in Figure 11 or a sequence which hybridises thereto under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions.

99. (Previously presented). A method according to claim 95 in which the enhancer element comprises a sequence comprising nucleotides 14760 to 15091 as shown in Figure 11 or a sequence which hybridises thereto under high stringency 0.1 x SSC and 0.1% (w/v) SDS at 50°C wash conditions.

100. (Previously presented). A method according to claim 95 in which the promoter is selected from the group consisting of a herpes virus thymidine kinase (TK) promoter, a Rous sarcoma virus (RSV) promoter, a promoter active in the prostate, or a promoter active in the vascular endothelium.

101. (Previously presented). A method according to claim 100 in which the promoter active in the prostate is selected from the group consisting of a probasin promoter, a PSM promoter and a PSA promoter.

102. (Previously presented). A method according to claim 101 in which the promoter active in the prostate is a PSM promoter.

103. (Cancelled).

104. (Cancelled).

105. (Cancelled).

106. (Previously presented). A method according to claim 95 in which the coding sequence encodes the enzyme purine nucleoside phosphorylase (PNP).

107. (Currently amended). A method for directing *in vitro* expression of a coding sequence in a cell, the method comprising introducing into the cell a recombinant expression cassette comprising at least one enhancer element obtained from intron 3 of the PSM gene, a promoter, and a coding sequence, wherein the enhancer~~regulatory~~ element and promoter direct expression of the coding sequence.

108. (New). The method according to claim 85 in which the coding sequence encodes a toxin, a protein involved in viral replication, or an enzyme which converts a prodrug to a toxic drug.

109. (New). The method according to claim 108 in which the coding sequence encodes an enzyme which converts a prodrug to a toxic drug.

110. (New). The method according to claim 109 in which the enzyme is purine nucleoside phosphorylase (PNP).

111. (New). The method according to claim 95 in which the coding sequence encodes a toxin, a protein involved in viral replication, or an enzyme which converts a prodrug to a toxic drug.

112. (New). The method according to claim 111 in which the coding sequence encodes an enzyme which converts a prodrug to a toxic drug.

113. (New). The method according to claim 112 in which the enzyme is purine nucleoside phosphorylase (PNP).